

THE 340B PROGRAM HANDBOOK

Integrating 340B into the
Health-System Pharmacy
Supply Chain

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Dedication

The 340B Handbook

is dedicated

to my wife Janet

for her support through this
and the many professional
projects in our life together.

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Preface

The 340B program remains among the most significant supply chain savings opportunities for eligible nonprofit hospitals and government grantee clinics. Nearly 45% of U.S. hospitals participate in the 340B program ranging from small rural hospitals to the largest academic medical centers (AMCs) and integrated delivery networks (IDNs).^{1,2} The regulatory boundaries and operational requirements present a significant challenge to achieve results and mitigate risk. An active 340B program engages a broad spectrum of institutional resources in pharmacy, finance, compliance, and information technology, among others. The goal of community benefit for the care for the uninsured, underinsured, and low-income patients can be well-served through 340B program participation results.

Key elements of the 340B program are not fully outlined in law and regulation. Due to constraints on government oversight authority, formal regulatory guidance exists in only a few areas of the program. 340B program oversight by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) is supported through guidance documents, frequently asked questions (FAQs) posted on HRSA and Apexus web sites, a call center, and structured training programs through Apexus, the 340B Prime Vendor.

OPA fosters a view of compliance through on-site and desk audits with the primary result of program alignment across covered entities on key policy issues and compliance activities. The primary consequences of audit findings result in posting of violations on the HRSA web site and repayment of unearned 340B discount to manufacturers.³ OPA, Apexus, 340B Health, and numerous established and independent consultants provide support to 340B program participants, primarily by offering compliance-focused and policy-based solutions.

Pharmacy leaders in 340B hospitals experience a strong tension between meeting detailed and complex 340B compliance requirements as well as supporting technical supply chain efficiency and effectiveness goals, including drug shortages and achieving health-system financial objectives. Drug shortages, formulary changes, supply chain efficiency, and other operating concerns are amplified and complicated by 340B. In addition to health-system operations challenges, the complexities of pharmacy regulation, including state board and Drug Enforcement Administration (DEA) requirements and the requirements of the Drug Supply Chain Security Act (DSCSA), must also be considered.

The 340B Program Handbook is designed as a practical guide for pharmacy leaders, hospital administrators, business managers, and pharmacy supply chain professionals implementing, maintaining, or overseeing a high-performing 340B program. *The 340B Handbook* content focuses on financial, business, and supply chain performance constraints and opportunities in the face of unique 340B options and compliance constraints.

The Handbook is designed to offer well-organized, practical information that considers and integrates 340B into the current care delivery model, information systems, and the increasingly complex healthcare supply chain beyond 340B. In seeking 340B advice, hospitals generally engage “340B experts” and receive guidance that honors 340B program requirements. In contrast, the *Handbook* assembles a group of professionals who work with 340B every day to provide a framework for building and managing an effective contemporary supply chain that integrates 340B program requirements.

ASHP members in pharmacy leadership positions (vice presidents, directors of pharmacy, assistant directors of pharmacy), pharmacy business managers, supply chain leaders, and health-

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system compliance officers outside pharmacy should find the *Handbook* to be a practical guide to implementing 340B and as a support in managing leadership conversations regarding 340B program expectations.

Andrew L. Wilson, PharmD, FASHP

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Andrew L. Wilson

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